

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	)	Before the Examiner
	)	Leonard Schenkman
Stephen R. ASH	)	
	)	Group Art Unit 1614
Serial No.: 08/869,331	)	
	)	
Filed: June 5, 1997	)	
	)	
METHOD FOR IRON DELIVERY TO A	)	
PATIENT BY TRANSFER FROM	)	
DIALYSATE	)	August 14, 1998

VERIFICATION OF  
SMALL ENTITY STATUS

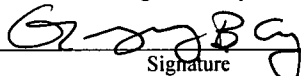
BOX ISSUE FEE  
Assistant Commissioner for Patents  
Washington, DC 20231

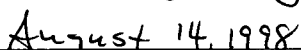
Sir:

The Applicant tenders herewith a fresh Statement Claiming Small Entity Status for Independent Inventor, for Small Business Concern as to HemoCleanse, Inc., and a new Statement Claiming Small Entity Status for Small Business Concern as to R&D

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on August 14, 1998.

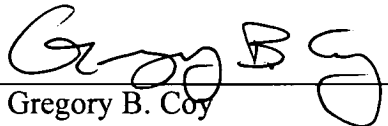
GREGORY B. COY  
Name of Registered Representative

  
Signature

  
Date of Signature

Laboratories, Inc. While small entity status has not changed for this case, a third party now owns rights in the invention. Therefore, the basis for small entity status has changed and is supported by the enclosed statements.

Respectfully submitted

By:   
Gregory B. Coy  
Reg. No. 40,967  
Woodard, Emhardt, Naughton,  
Moriarty & McNett  
Bank One Center/Tower  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
(317) 634-3456

**STATEMENT CLAIMING SMALL ENTITY STATUS**  
**(37 CFR 1.9(f) & 1.27(c))—SMALL BUSINESS CONCERN**

Docket Number (Optional)  
11002-29

Applicant, Patentee, or Identifier: Stephen R. ASH  
Application or Patent No.: 08/869,331  
Filed or Issued: June 5, 1997  
Title: METHOD FOR IRON DELIVERY TO A PATIENT BY TRANSFER FROM DIALYSATE

I hereby state that I am

- ☐ the owner of the small business concern identified below.  
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN R & D Laboratories, Inc.

ADDRESS OF SMALL BUSINESS CONCERN 4640 Admiralty Way, Suite 710  
Marina Del Ray, CA 90292

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

- ☐ the specification filed herewith with title as listed above.  
☒ the application identified above.  
☐ the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

- Each person, concern, or organization having any rights in the invention is listed below:  
☐ no such person, concern, or organization exists.  
☒ each such person, concern, or organization is listed below.

Hemocleanse, Inc.

Separate statements are required from each named person, concern or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Rhoda Makoff  
TITLE OF PERSON IF OTHER THAN OWNER PRESIDENT / CEO  
ADDRESS OF PERSON SIGNING 4640 ADMIRALTY WY MAR CA 90292  
SIGNATURE Rhoda Makoff DATE 8/10/98

**STATEMENT CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(c))--SMALL BUSINESS CONCERN**

Docket Number (Optional)  
11002-29

Applicant, Patentee, or Identifier: Stephen R. ASH  
Application or Patent No.: 08/869,331  
Filed or Issued: June 5, 1997  
Title: METHOD FOR IRON DELIVERY TO A PATIENT BY TRANSFER FROM DIALYSATE

I hereby state that I am

- ☐ the owner of the small business concern identified below.  
☒ an official of the small business concern empowered to act on behalf of the concern identified below.

NAME OF SMALL BUSINESS CONCERN HemoCleanse, Inc.

ADDRESS OF SMALL BUSINESS CONCERN 2700 Kent Avenue  
West Lafayette, IN 47906

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

- ☐ the specification filed herewith with title as listed above.  
☒ the application identified above.  
☐ the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

- Each person, concern, or organization having any rights in the invention is listed below:  
☐ no such person, concern, or organization exists.  
☒ each such person, concern, or organization is listed below.

R & D Laboratories, Inc.

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NAME OF PERSON SIGNING Robert B. Truitt

TITLE OF PERSON IF OTHER THAN OWNER President

ADDRESS OF PERSON SIGNING 2700 KENT AVE, N. LAFAYETTE, IN 47906

SIGNATURE Robert B. Truitt DATE 8/5/98

**STATEMENT CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR**

Docket Number (Optional)

11002-29

Applicant, Patentee, or Identifier: Stephen R. ASH

Application or Patent No.: 08/869,331

Filed or Issued: June 5, 1997

Title: METHOD FOR IRON DELIVERY TO A PATIENT BY TRANSFER FROM DIALYSATE

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

☐ the specification filed herewith with title as listed above.

☒ the application identified above.

☐ the patent identified above.

I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☐ No such person, concern, or organization exists.

☒ Each such person, concern, or organization is listed below.

HemoCleanse, Inc.

2700 Kent Avenue

West Lafayette, IN 47906

R & D Laboratories, Inc.

4640 Admiralty Way, Suite 710

Marina Del Ray, CA 90292

Separate statements are required from each named person, concern, or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

Stephen R. ASH

NAME OF INVENTOR

NAME OF INVENTOR

NAME OF INVENTOR

Signature of inventor

Signature of inventor

Signature of inventor

Date

Date

Date

Docket No.  
11002-29

# Declaration and Power of Attorney For Patent Application

## English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

METHOD FOR IRON DELIVERY TO A PATIENT BY TRANSFER FROM DIALYSATE  
the specification of which

(check one)

☒ is attached hereto.

☐ was filed on \_\_\_\_\_ as United States Application No. or PCT International  
Application Number \_\_\_\_\_  
and was amended on \_\_\_\_\_  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
			<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

<u>60/023,926</u>	<u>August 14, 1996</u>
(Application Serial No.)	(Filing Date)

_____	_____
(Application Serial No.)	(Filing Date)

_____	_____
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)

_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)

_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

Harold R. Woodard 16,214; C. David Emhardt 18,483; Holiday W. Banta 40,311; Troy J. Cole 35,102; L. Scott Joseph A. Naughton 19814; John V. Moriarty 26,207; Paynter 39,797; J. Andrew Lowes P40,706; Matthew R. John C. McNett 25,533; Thomas Q. Henry 28,309; James Schantz P40,800; Gregory B. Coy P40,967; Lisa Hiday M. Durlacher 28,840; Charles R. Reeves 28,750; Vincent 40,036; John V. Daniluck P40,581 O. Wagner 29,596; Steve Zlatos 30,123, Spiro Bereveskos 30,821; William F. Bahret 31,087; Clifford W. Browning 32,201; R. Randall Frisk 32,221; Daniel J. Lueders 32,581; Michael D. Beck 32,722; Kenneth A. Gandy 33,386; Timothy N. Thomas 35,714; Kerry P. Sisselman 37,237; Kurt N. Jones 37,996; John H. Allie 39,088; Jeffrey A. Michael 37,394; Deborah K. Knoll 37,370;

Send Correspondence to: Kenneth A. Gandy  
Woodard, Emhardt, Naughton, Moriarty & McNett  
111 Monument Circle, Suite 3700  
Indianapolis, IN 46204

Direct Telephone Calls to: *(name and telephone number)*  
317-634-3456

Full name of sole or first inventor	
Stephen R. Ash	
Sole or first inventor's	Date
3736 Pershing Drive, Lafayette, Indiana 47905	
Residence	
USA	
Citizenship	
3736 Pershing Drive, Lafayette, Indiana 47905	
Post Office Address	

Full name of second inventor, if any	
Second inventor's signature	Date
Residence	
Citizenship	
Post Office Address	

08869331 060597



Applicant or Patentee: Stephen R. Ash

Serial or Patent No.: 60/023,926

Filed or Issued: August 14, 1996

For: METHOD FOR IRON MAINTENANCE FOR ESRD PATIENTS BY TRANSFER FROM DIALYSATE

Attorney's

Docket No.: 11002-23

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) and 1.27(c))- SMALL BUSINESS CONCERN

I hereby declare that I am

- ☐ the owner of the small business concern identified below:  
☒ an official of the small business entity empowered to act on behalf of the concern identified below:

NAME OF CONCERN: Hemocleanse, Inc.  
ADDRESS OF CONCERN: 2700 Kent Avenue  
West Lafayette, IN 47906

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for the purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled METHOD FOR IRON MAINTENANCE FOR ESRD PATIENTS BY TRANSFER FROM DIALYSATE described in

- ☐ the specification filed herewith.  
☒ application Serial No. 60/023,926, filed August 14, 1996.  
☐ Patent No. \_\_\_\_\_, issued \_\_\_\_\_.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who would not qualify as a small business concern under 37CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

\*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

0886931-060597

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful and false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

HEMOCLEANSE, INC.

By Robert B. Truitt  
Robert B. Truitt, President

Date 8/19/96

265099 " F E E 9830

Applicant or Patentee: Stephen R. Ash

Serial or Patent No.: 60/023,926

Filed or Issued: August 14, 1996

For: METHOD FOR IRON MAINTENANCE FOR ESRD PATIENTS BY TRANSFER FROM DIALYSATE

Attorney's

Docket No.: 11002-23

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) and 1.27(b))- INDEPENDENT INVENTOR

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled METHOD FOR IRON MAINTENANCE FOR ESRD PATIENTS BY TRANSFER FROM DIALYSATE described in

☐ the specification filed herewith

☒ application Serial No. 60/023,926 filed August 15, 1996

☐ Patent No. \_\_\_\_\_, Issued \_\_\_\_\_

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). Each person, concern or organization to which I have assigned granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☐ no such person, concern or organization

☐ persons, concerns or organizations listed below\*

\*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME Hemocleanse, Inc.

ADDRESS 2700 Kent Avenue

West Lafayette, IN 47906

☐ INDIVIDUAL ☒ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful and false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Date

8/19/96

Stephen R. Ash